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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,656	12/21/2001	Clive Patience	329579-3	5770

7590 04/20/2004

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,656	PATIENCE ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18, 20-33, 35-39, 41-46, 48-62* is/are pending in the application.

4a) Of the above claim(s) *1-6,8-18,20-33,35-39,41-46,48-51 and 58-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 52-57* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In the paper submitted October 14, 2003, applicant amended claims 7, 33, 38, 39, 41, 46, 52, cancelled claims 19, 34, 40, 47, and added new claims 56-62. Claims 1-18, 20-33, 35-39, 41-46, 48-62 are pending in the application.

Election/Restrictions

Newly submitted claims 58-62 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: Claim 58 encompasses the subject matter of group XIV, drawn to a method of identifying a compound that interferes with PERV-binding to a cell by contacting a compound with a PERV receptor, classified in class 435, subclass 32. New claims 59 and 60 depend from the claims of group XVII, drawn to a process for blocking a PERV receptor on a cell by contacting the receptor with an agent, classified in class 435, subclass 7.2. New claim 61 encompasses the subject matter of group XVIII, drawn to a method of protecting against PERV infection, classified in class 424, subclass 184.1. Finally, new claim 62 is drawn to the subject matter of group XX, drawn to a transgenic animal, classified in class 800, subclass 3. It is noted that the previous restriction erroneously classified this last group XX. The correct classification is class 800, subclass 3.

These inventions remain patentably distinct for the reasons stated in the restriction requirement of paper no. 5:

The instant process of group XIV can be used with any of the structurally distinct receptor products claimed in groups I-III, IV-VII. The process of group XVII can be accomplished with any receptor claimed in claims IV-VII, and with any antibody of groups VIII-XIII or any agent bearing no structural or functional similarity to the instant

antibodies. The process of group XVIII, protecting against PERV infection can be practiced with any agent that binds to various PERV receptors or any specific antibody claimed in groups VIII-XIII. Finally, group XX is drawn to a transgenic animal that is structurally and functionally distinct from the nucleic acids, polypeptides, and antibodies of groups I-III, IV-VII and VIII-XIII, respectively. These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 58-62 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Accordingly, this application contains claims 1-18, 20-33, 35-39, 41-46, 48-51 and 58-62 are drawn to an invention nonelected with traverse in Paper No. 7. In addition, claim 7 recites patentably distinct SEQ ID NOs: 12, 16, 17 and immunogenic fragments thereof, that were withdrawn from consideration due to a nonelection with traverse. A complete reply to the final rejection must include cancelation of claims and subject matter drawn to nonelected inventions or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The status of the claims is as follows: Claims 1-18, 20-33, 35-39, 41-46, 48-62 are pending. Claims 1-6, 8-18, 20-33, 35-39, 41-46, 48-51 and 58-62 are withdrawn from consideration due to nonelected subject matter. Claims 7 (SEQ ID NO: 14) and 52-57 are under consideration.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claim 7 is objected to because of the following informalities: the acronym "PERV" should be spelled out before referencing the abbreviation. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 7 has been amended to recite a "kit" for screening, which comprises (a) the isolated polypeptide of SEQ ID NO: 14, fragments thereof, and (b) "instructions" for using the polypeptide for screening. Applicant states on page 14 of the response that support for the new claims is found throughout the specification, but especially on page 15, Table 1 and page 23, lines 16-19. However, the examiner is unable to find explicit or

implied support for the "kit" or the "instructions for using" the polypeptide for screening in the disclosure. On page 20, line 5 to page 21, line 9, the disclosure discusses a screening assay and a process for identifying agents that are able to interfere with PERV binding to cells expressing PERV-receptors, where the PERV-receptor comprises SEQ ID NO: 14 or an active fragment thereof (page 21, lines 5-9). The process discussed in the disclosure employs active steps, but does not include a "kit" or "instructions for using". The screening assay on page 20 of the disclosure does not include "instructions for using". Therefore, the screening assay does not provide adequate support for the claimed kit. Applicant is required to either point to support in the specification for where these limitations can be found in the disclosure or cancel the new matter presented.

Claims 52-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising SEQ ID NO: 14, or immunogenic fragments thereof, specifically binding to PERV-A, does not reasonably provide enablement for a polypeptide comprising SEQ ID NO: 14, or immunogenic fragments thereof, specifically binding to any retrovirus or other PERV retroviruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims and the nature of the invention

The claims encompass an isolated polypeptide comprising 85% to 100% of SEQ ID NO: 14, or immunogenic fragments thereof, that specifically bind to any retrovirus.

The state of the prior art

Takeuchi et al. (Journal of Virology. 1998; 72 (12): 9986-9991) teach transfecting pre-infected and uninfected cell lines with various PERV strains as well as other type C retroviruses. The data of Takeuchi et al. clearly demonstrate that PERV viruses bind to receptors that are different from other type C retroviruses, see "Cross-interference..." bridging pages 9988-9989 and Table 2.

Ericsson et al. (PNAS. May, 2003; 100 (11): 6759-6764) identify PERV receptors and teach that the receptors used by PERV-A , -B and -C are distinct from the receptors

used by each other and other retroviruses, "Receptor Tropism..." bridging pages 6761-6763 and Figure 2.

The level of one of ordinary skill

While the ordinary artisan would be able to use a polypeptide comprising 85% to 100% of SEQ ID NO: 14, or immunogenic fragments thereof, to specifically bind a PERV-A retrovirus, it is beyond the skill in the art to use the instant polypeptides to bind to other PERV strains or any other retroviruses.

The level of predictability in the art

Since the art does not disclose any other retrovirus that requires the PERV-A receptor of SEQ ID NO: 14 for entry and infectivity, the skilled artisan would be unable to predict, in the absence of proof to the contrary, that the instant polypeptide, or immunogenic fragments thereof, would bind any other retrovirus besides PERV-A.

The amount of direction provided by the inventor

The disclosure identifies SEQ ID NO: 14 as a PERV-A receptor, see page 14, lines 18-25, but does not teach how to use this receptor to bind other retroviruses. The skilled artisan is not provided with sufficient guidance from the disclosure to specifically bind retroviruses to the instant polypeptide, other than PERV-A.

The existence of working examples

Example 1 demonstrates that the receptors used by the different PERV viruses are distinct.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). There is insufficient evidence to support applicant's claims that SEQ ID NO: 14, or immunogenic fragments thereof, would bind any retrovirus other than PERV-A. There is no working example or data from the art that would indicate that the PERV-A receptor of SEQ ID NO: 14 is required by other retroviruses. Therefore, it is determined that an undue quantity of experimentation would be required of the skilled artisan to use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 52-57 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by a sequence alignment of SEQ ID NO: 14 with SPTREMBL_21 database accession number Q9NWF4 of Isogai et al. submitted October 1, 2000 for reasons of record.

Applicant argues that the sequence disclosed by Isogai et al. does not suggest that the sequence is a PERV receptor or binds to a retrovirus.

Applicant's arguments have been fully considered, but are found unpersuasive. The discovery of a previously unappreciated characteristic of a prior art composition does not render an old product newly patentable. Inherent characteristics disclosed within a prior art reference are not required to be appreciated or recognized for the reference to be anticipatory. *Atlas Power Co. v. IRECO Inc.*, 190 F.3d 1342, 51 USPQ2d 1943 (Fed. Cir. 1999. Additionally, the courts have determined that "[I]nherency is not necessarily coterminus with the knowledge of those of ordinary skill in the art." See *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). That is, it need not have been appreciated or recognized that the prior art reference inherently discloses the same invention for the reference to be anticipatory. In the instant case, the claims are drawn to a sequence with a particular function. Although Isogai et al. do not associate a function with the polypeptide sequence disclosed, the sequence of Isogai et al. necessarily possesses all of the structural requirements necessary for the claimed function. Therefore, the polypeptide sequence of Isogai et al. anticipates the instant polypeptide.

Conclusion

Regarding claim 7, applicant correctly points out that Isogai et al. do not disclose a property of the protein besides its sequence structure. Therefore, there is no motivation to add the protein of Isogai et al. into a kit recited in claim 7. Claim 7 also requires instructions for using the polypeptide. It is noted that the "instructions" are a physical component of the claimed kit, but are not patentable because they are not functionally

related to the instant polypeptide, see *In re Gulack*, 703 F.2d 1381, 217 USPQ 401 (Fed. Cir. 1983). However, there is no motivation to include the sequence of Isogai et al. with printed matter of any sort. Nonetheless, the instantly claimed "kit" and the "instructions for using" present new matter.

Applicant's statement that European Patent EP 1074617-A2 would have to be asserted as prior art due to the publication date is acknowledged. However, the EP document teaches the same sequence structure as Isogai et al. and is seen as a cumulative teaching. EP 1074617-A2 contains the exact same residue difference and the exact same sequence identity (99.8%) to the instant SEQ ID NO: 14 as the sequence of Isogai et al. Further, the EP document has a publication date of February 7, 2001, while the submission date of Isogai et al. is October 1, 2000, which is 4 months and 6 days prior to EP1074617-A2. Therefore, the 2-page database disclosure of Isogai et al. is chosen for citation rather than the 2537-page EP reference.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

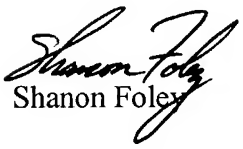
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shanon Foley